RECEIVED OPPT CBIC



2011 AUG 25 AM 11: 03

Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419-8300 www.syngenta.com

Tel. 336 632-6000

FEDERAL EXPRESS

REDACTED COPY

MR#337715

August 24, 2011

U.S. Environmental Protection Agency **EPA East Building** Confidential Business Information Center Room 6428 Attn: TSCA Section 8(e) 1201 Constitution Avenue, NW Washington, DC 20004



RE: TSCA Section 8(e) Notice: AMENDMENT TO CORRECT THE LETTER PREVIOUSLY SUBMITTED ON AUGUST 12, 2011 - Rabbit Preliminary Developmental Study with [1. a Substituted Benzamide, Fifth Submission

Dear TSCA Section 8(e) Coordinator:

Syngenta Crop Protection, LLC submitted a letter on August 12, 2011, whose subject line/title indicated it was the "FOURTH SUBMISSION," concerning the substance, [], when in fact, it should have read, "FIFTH SUBMISSION." Please accept the enclosed letter, as a replacement to the one that you currently have. The subject line/title of the enclosed letter has been corrected to read:

"Rabbit Preliminary Developmental Study with [

1, a Substituted Benzamide, Fifth Submission."

There are no other changes to the content of the letter.

Syngenta Crop Protection, LLC requests that the specific chemical identity and code number shown in brackets in this letter, and the enclosed amended letter be treated as Confidential Business Information. We enclose a redacted copy of the corrected letter for the public file.

Should you have questions regarding the correction made to the letter, please contact me at (336) 632-6470.

With kindest regards,

Kimberly York Regulatory Specialist

Syngenta Crop Protection, LLC

Enclosure

RECEIVED OPPT CBIC

2011 AUG 25 AM 11: 03

Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419-8300 www.syngenta.com Tel. 336 632-6000



FEDERAL EXPRESS

REDACTED COPY

August 12, 2011

U.S. Environmental Protection Agency EPA East Building Confidential Business Information Center Room 6428 Attn: TSCA Section 8(e) 1201 Constitution Avenue, NW Washington, DC 20004

Re: TSCA Section 8(e) Notice:

Rabbit Preliminary Developmental Study with [], a Substituted Benzamide, Fifth Submission

Dear TSCA Section 8(e) Coordinator:

Syngenta Crop Protection, LLC requests that the specific chemical identity and code number shown in brackets in this letter be treated as Confidential Business Information. We enclose a redacted copy of this letter for the public file.

In accordance with EPA's March 16, 1978 policy on Section 8(e) reporting under the Toxic Substances Control Act, and EPA's June 1991 TSCA Section 8(e) Reporting Guide, Syngenta Crop Protection is bringing to your attention information from a preliminary developmental toxicity study in the rabbit conducted with the chemical substance []. This substance is known internally under the designation [].

In a preliminary developmental toxicity study, groups of 10 NZW female rabbits were dosed with at levels of 0, 5, 15 and 30 mg/kg bw/day in vehicle 0.5% CMC, by oral gavage from gestation day 6 to 27. At 30 mg/kg bw/day, one female on gestation day10 was observed convulsing. The animal recovered and no other clinical signs were recorded for this animal. At the same dose level, two females were terminated (days 13 and 14 of gestation respectively) due to loss of use of hind limbs. At necropsy these animals had red material in the cranial cavity, lumbar region of the spinal column and red frothy material in the trachea. At this point the top dose group was terminated on animal welfare grounds. Animals in all groups, including the controls were noted as difficult to dose and showed reduced feces. There were no other treatment related clinical observations at any other dose level. The study is being referred since deaths were observed at a lower dose level than previously reported.

[] is a research and development compound being evaluated for pesticidal purposes. These evaluations are being conducted under the supervision of technically qualified personnel, knowledgeable in handling potentially hazardous chemicals.

Please contact the undersigned if you require additional information.

Sincerely,

Melvin R. Witcher, Jr., CIH
Melvin R. Witcher, Jr.

TSCA Coordinator

Syngenta Crop Protection